

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  Liu et al.  Serial No.: 10/813,483  Filed: March 29, 2004  For: HIGH CONCENTRATION ANTIBODY AND PROTEIN FORMULATIONS	Group Art Unit: 1644  Examiner: Kim, Yunsoo  Confirmation No: 5594  CUSTOMER NO: 09157  <b>Electronically Filed August 31, 2007</b>
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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

**[X] 37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491, **or**
- before the mailing of the first Office action on the merits; **or**
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

☐ **37 CFR §1.97(d)**

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) and/or publication(s) is set forth on the attached revised Form PTO-1449.

Copies of the items listed on the PTO-1449 form are supplied herewith, except for United States patent(s) and United States patent application publication(s) and other documents that are marked with an asterisk (\*) in the attached PTO-1449 form. Copies of United States patents and United States patent application publications will not be supplied unless requested by the Office [37 CFR §1.98(a)(2)(ii)]. See Final Rule **1287 OG** (October 12, 2004). However, copies of any cited document will be provided in its entirety at the request of the Office.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

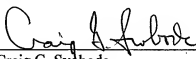
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The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630.

Respectfully submitted,  
GENENTECH, INC.

Date: August 31, 2007

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FORM PTO-1449	U.S. Dept. of Commerce Patent and Trademark Office	Atty Docket No. P2026R1	Serial No. 10/813,483
LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)		Applicant Liu et al.	
		Filing Date 29 Mar 2004	Group 1644

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	43	4,093,606	06.06.78	Coval, M.			
	44	4,499,073	12.02.85	Tenold, R.			
	45	4,877,608	31.10.89	Lee, T. et al.			
	46	4,940,782	10.07.90	Rup et al.			
	47	5,036,049	30.07.91	Audhya, T. et al.			
	48	5,096,885	17.03.92	Pearlman et al.			
	49	5,215,743	01.06.93	Singh, M. et al.			
	50	5,262,296	16.11.93	Ogawa, E. et al.			
	51	5,399,670	21.03.95	Bhattacharya, P. et al.			
	52	5,580,856	03.12.96	Prestrelski et al.			
	53	5,612,315	18.03.97	Pikal et al.			
	54	5,849,700	15.12.98	Sorensen et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes	No
	55	0531539	03.06.98	EP				
	56	303746	22.02.89	EP				
	57	391444	10.10.90	EP				
	58	597,101	18.05.94	EPO				
	59	841,067	13.05.98	EPO				
	60	96/20202	04.07.96	PCT				
	61	97/45140	04.12.97	PCT				
	62	WO 89/11297	30.11.89	PCT				
	63	WO 90/11091	04.10.90	PCT				
	64	WO 93/05799	01.04.93	PCT				

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	65	Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations" <u>Pharmaceutical Research</u> 8(3):285-291 (1991)
	66	Bam et al., "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique" <u>Pharm. Res.</u> 12:2-11 (1995)
	67	Cleland et al., "Development of Stable Protein Formulations for Microencapsulation in Biodegradable Polymers" <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> 22:514-515 (1995)
	68	Cleland et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation" <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> 10(4):307-377 (1993)
	69	Draber et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose" <u>Journal of Immunological Methods</u> 181(1):37-43 (1995)
	70	Manning et al., "Stability of Protein Pharmaceuticals" <u>Pharm. Res.</u> 6(11):903-918 (1989)

Examiner	Date Considered
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P2026R1

Serial No.

10/813,483

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Liu et al.

Filing Date

29 Mar 2004

Group

1644

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

71	Nielsen, et al., "Stability of Freeze Dried Horseradish Peroxidase Conjugated Monoclonal Antibodies Used in Diagnostic Serology" <u>Journal of Immunoassay</u> 16(2):183-197 (1995)
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72	Pearlman et al., "Analysis of Protein Drugs" <u>Peptide and Protein Drug Delivery</u> , Vincent H. L. Lee, Marcel Dekker, Inc., Chapter 6, pps. 247-301 (1991)
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73	Pikal et al., "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone" <u>Pharm. Res.</u> 8:427-436 (1991)
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74	Wang et al., "Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers" <u>J. Parenteral Sci. Tech.</u> (Technical Report No. 10) 42(2S):S4-S26 (1988)
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Examiner

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